

Attorney Docket No. 044170-5052-01

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Amendments to the Claims:

In the Office Action the Examiner indicated the claims had been renumbered beginning with claim 58. This listing of claims will replace all prior versions and listings of claims in the application:

Claims 1-49 (cancelled).

Claim 50. (currently amended) A device for collecting and assay of fluids, comprising:
a housing having a fluid receiving end and an assay portion;
a lateral flow assay strip contained substantially within the assay portion, the assay strip containing at least one reagent that is used to detect one of the presence and absence of at least one analyte in a fluid; and
a collection strip for transporting the fluid from a fluid source to the assay strip, the collection strip including:
a first, narrow end contained within the housing and in fluid communication with the assay strip, and
a second, enlarged end protruding from the fluid receiving end; and
a blocking strip coupled between and in flow communication with the lateral flow assay strip and the collection strip.

Claim 51. (previously presented) The device of claim 50, wherein the collection strip comprises a capillary matrix adapted for rapid wicking of fluid from a fluid source to the assay strip.

Claim 52. (previously presented) The device of claim 50, wherein the fluid source is an oral cavity.

Claim 53. (previously presented) The device of claim 50, wherein the second end is one of a paddle-shape and substantially bulbous shape.

Claim 54. (currently amended) A device for assay of oral fluid, comprising:
an assay portion housing a lateral flow assay strip, the assay strip containing at least one reagent that is used to detect one of the presence and absence of at least one analyte in a fluid; and

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a neck portion extending from the assay portion, the neck portion forming a channel for delivery of fluid to the assay strip, the channel being defined by a first, narrow part proximal to the assay portion and a second part including an opening for receiving the oral fluid, wherein the second part includes a channel width that is substantially wider than the channel width at the narrow end; and

a wicking member collection strip in fluid communication with the lateral assay strip, the wicking member collection strip having a first portion disposed within the channel and a second portion protruding outwardly from the neck portion opening; and

a blocking strip coupled between and in flow communication with the lateral flow assay strip and the collection strip.

Claim 55. (previously presented) The device of claim 54, wherein the wicking member second portion is paddle shaped.

Claim 56. (previously presented) The device of claim 54, wherein the width of the neck portion tapers from the opening width to the narrow end width.

Claim 57. (withdrawn) A method for rapid collection and assay of oral fluids, comprising the steps of

forming an assay device including a lateral flow assay strip, a capillary matrix in fluid communication with the assay strip, and a body for housing the assay strip, wherein at least a portion of the capillary matrix protrudes outwardly from the assay device;

placing the assay device in an oral cavity;

removing the assay device from the oral cavity; and

reading the test results.

Claim 58 (previously presented) The device of claim 50, wherein the assay strip is an immunochromatography strip.

Claim 59. (previously presented) The device of claim 50, further comprising a sample adequacy indicator.

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Claim 60. (previously presented) The device of claim 50, wherein the reagent is an immunospecific binding partner which bears a detectable label.

Claim 61. (currently amended) The device of claim 59 60, wherein the reagent is an enzyme labeled binding partner.

Claim 62. (previously presented) The device of claim 50, wherein the reagent comprises one of an antigen and an antibody.

Claim 63. (new) The device of claim 54, wherein the blocking strip contains at least one blocking agent or a buffer.

Claim 64. (new) The device of claim 50, wherein the blocking strop contains at least one blocking agent or a buffer.

Claim 65. (new) The device of claim 54, wherein the collection strip is adsorbent.

Claim 66. (new) The device of claim 50, wherein the collection strip is adsorbent.